October 22, 2004

Additional EPA comments (received on 9/22/04) on Ecological TRVs and LWG Responses

EPA Comments and LWG Responses

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LWG Response: The LWG disagrees that it is premature to screen out aluminum and manganese based on background. These two compounds are crustal elements. In addition, the toxicity studies in the literature are based on a form of aluminum and manganese that is not typically found in environmental samples; therefore, any TRV developed will not be comparable to environmental samples. If compared, environmental samples will appear "toxic" since the form used in the lab is much more bioavailable than the total aluminum and manganese found in the environmental samples. To address this EPA comment, the LWG has provided the literature and our review of the literature. No provisional TRV was selected because of the lack of environmental relevance of the aluminum and manganese chemical forms in the reviewed studies. The literature references are provided for EPA and EPA's partners to review and discuss.

PAHs - The LWG has agreed to evaluate the scientific literature in order to develop a relationship between PAH sediment concentrations and occurrence of lesions in fish resulting from dermal contact.

LWG Response: The LWG has reviewed the PAH literature suggested by EPA and has a discussion of the evaluation provided in the literature. LWG has not developed provisional TRVs based on dermal contact due to the lack of a clear cause-and-effect linkage of effects-based values and due to the uncertainty of the data.

Dietary TRVs - The LWG will attempt to develop dietary TRVs for metals (including mercury), DDT and PCBs

LWG Response: LWG has developed dietary TRVs for the following fish COIs: arsenic, cadmium, copper, lead, selenium, zinc, PAHs, TBT, DDT, PCBs, and mercury. A literature search was conducted for the following fish COIs; however, no toxicological literature was available or toxicological literature could not be used to develop a dietary TRV: aluminum, antimony, chromium, nickel, and thallium.

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LWG Response: This comparison will be completed in the PRE as part of data evaluation.

In addition to the above issues, EPA has identified a number of other issues based on a review of the LWG's July 16, 2004 response to EPA Comments on TRV Selection Technical Memorandum. A spreadsheet comparing TRVs proposed by the LWG to literature TRVs and a graph that presents a range of TRVs have been included as attachments.

G3 - Lines of Evidence: For chemicals for which both a dietary approach and a tissue residue approach will be pursued, the TRV TM should provide general information on how these two approaches will be used to evaluate effects on ecological receptors through a line of evidence or weight of evidence approach.

LWG Response: The LWG agrees with this comment. Text has been added to the document (see paragraph two of Section 2.1 of the TRV Tech Memo).

G 5 - Lack of TRVs: The revised TRV TM should consider the following approaches to establish a TRV where one is lacking:

Develop TRVs from acute LD50 values using an appropriate uncertainty factor. There is literature where an LD50 with an uncertainty factor

of up to 10,000 provides a "ballpark" estimate of a chronic TRV. See paper by Layton et al.1987.

LWG Response: A factor of 10 was used to develop a LOEC or LOAEL TRV from an LC50. This value is commonly used as a conversion in ecological assessments (e.g., AWQC acute-to-chronic ratio).

Structural similarity to another compound may allow use of a surrogate TRV. Endrin for endrin aldehyde for example.

LWG Response: Surrogates were used (e.g., endrin for endrin aldehyde, heptachlor for heptachlor epoxide) for related compounds when no toxicity data were available (see Table 2).

Chemical class toxicity. Example: Phthalate esters. Can use the TRV for the most toxic phthalate ester to apply to a phthalate compound lacking toxicity data. This is conservative, but this is not inappropriate for a PRE.

LWG Response: Chemical classes (i.e., phthalates and phenols) were used to represent TRVs for chemicals in the class for which no toxicological literature was available (see Table 2).

Look at TRVs for other orders or families of organisms and attempt to do body weight scaling of an existing TRV for extrapolation to the receptor (such as river otter) lacking a TRV. EPA recommends against performing allometric scaling for any bird species.

LWG Response: This extrapolation is not relevant to chemical surrogates; however, it is relevant to species surrogates. This type of analysis may be more appropriate in the Baseline ERA.

Graph the NOAELs and LOAELs for structurally related compounds across different organisms and use judgment to select values to bound the potential toxicity for receptors where a more relevant TRV is lacking.

LWG Response: Scatterplots were developed for each chemical, if enough data were available. We did not graph across different organisms and chemicals. This type of analysis may be useful in an exploratory sense and could be evaluated as part of the Baseline ERA.

Calculate TRVs using the product of a chronic ambient water quality criteria and a bioconcentration factor. Such an approach could be a fallback methodology for chemicals where a residue based TRV is desired but where little or no residue-effects data are available in

the literature.

LWG Response: This approach has increased uncertainty due to the number of assumptions made. Please review the tissue TRVs that are proposed, based on measured concentrations associated with adverse effects. If discussion is needed regarding a particular compound, this can be further expanded in uncertainty section of the risk assessment.

G6 - Safety Factors: Our goal is to develop chronic TRVs. As a result, when no other option is available, we will need to apply safety factors to an acute study in order to obtain a chronic TRV. This is especially important for the preliminary risk evaluation. Further refinement of TRVs based on an acute to chronic conversion will be possible prior to development of the baseline risk assessment.

LWG Response: LWG agrees (please note that some conversions are highly uncertain because the original study has high uncertainty; see response to comment G16). Acute-to-chronic uncertainty factors were applied to LC50 studies (i.e., for fish WB residue TRVs for lindane and 4-methylphenol and for bird dietary TRVs for thallium and heptachlor).

G7 - Quality of Studies: EPA supports the concept of presenting scatter plots showing range of TRVs and selected TRV. This approach is conceptually similar to the species sensitivity distribution approaches used by numerous governments to develop environmental quality guidelines (e.g., EPA's methodology for deriving ambient water quality criteria). EPA recommends that the LWG consider developing a rank order of the TRVs and picking a low percentile of the rank-ordered data (such as the 5th percentile of the range) as the TRV. Such an approach has the advantage of using all of the information available from the literature the LWG has already compiled to derive TRVs, instead of relying on the findings of a single study for TRV development. It also generally results in a conservative TRV, which would be appropriate for use in the PRE. In addition, we have attached a graph showing how a range of TRVs may be presented.

LWG Response: LWG agrees (LWG will consider multiple ways of presenting and picking TRVs). Scatterplot figures (Figures 3-66) present the LOECs/LOAELs and NOECs/NOAELs reported in the reviewed studies. The 5th percentile of the LOEC or LOAEL is also presented in the figures if eight or more LOECs or LOAELs were developed from the reviewed literature.

G10 - Reproductive Endpoints for Salmonids and Lamprey: For the purposes of the PRE, reproductive endpoints should be considered for salmonids and lamprey. This represents a conservative approach appropriate for identifying contaminants and receptors on which to focus.

LWG Response: LWG disagrees (please note the assessment endpoint Table 2-9 of Appendix B in the approved work plan indicates that salmonids and lamprey

will be assessed using the growth and survival endpoints, per agreement with EPA and EPA's partners)

G16 - NOAEL/NOAEL Conversion: EPA does not understand the following statement: "Uncertainty factors will not be applied to unbounded LOECs derived for clams or crayfish due to the limited data available." Please provided additional clarification.

LWG Response: LWG agrees. Clarification will be added to the text (see Section 5.2.3.2). The LWG is highlighting the high LOECs due to limited studies, thus uncertainty is very high. Applying an uncertainty factor to these data will result in higher uncertainty.

S14 - Elimination of Studies from Consideration:

EPA agrees to eliminate studies with a lack of dietary concentrations from consideration of studies to be used in dietary TRV derivation, and lab studies involving mixtures (with the exception of chemicals that occur as mixtures such as PCBs and PAHs) from consideration of studies to be used in any TRV derivation.
Studies such as bioaccumulation studies, behavioral studies and studies measuring immunoresponse, biochemical and histopathological changes should be considered if those studies can be linked to effects on survival, growth or reproduction. Some bioaccumulation studies also explicitly state that the measured tissue residue has no significant effect on survival, growth or other toxicological endpoints of interest. If it is desired by LWG to compile no observed adverse effect level literature in addition to adverse effect level literature, EPA has no objection to using bioaccumulation studies for this purpose. Behavioral studies with endpoints such as predator avoidance, prey capture ability and swimming ability are among those most likely to be linked to survival, growth and reproduction, and should be considered during TRV derivation.

LWG Response: LWG agrees. NOTE: No studies were reviewed that linked immunoresponse, biochemical, and histopathological changes to survival, growth or reproduction, and therefore, no studies on these endpoints were included in the TRV selection process. Behavior studies and bioaccumulation studies are presented in the TRV, but generally were not used to develop TRVs (the reported behavior did not relate to survival, growth, or reproduction, or the bioaccumulation study did not measure or report a toxic effect).

Egg concentrations should be estimated from sediment concentrations though the application of appropriate partition coefficients.

LWG Response: LWG disagrees (LWG believes this is an exercise for the actual risk assessment (i.e., calculating exposure point concentrations), and should be discussed in the context of the actual risk calculation.

S45 - Invertebrate Tissue TRVs: EPA has identified invertebrate tissue as a key tissue data gap. Although there is a degree of uncertainty surrounding invertebrate TRVs, as there is with TRVs for any species, this information should be used in conjunction with benthic toxicity testing as another line of evidence. It is possible that invertebrate TRVs can be used to identify the chemical or chemicals that are responsible for the toxicity observed in the bioassays. EPA believes that for many chemicals, invertebrate and fish tissue based TRVs will be comparable to each other. This can be seen as the case for several of the LWG's proposed aquatic biota tissue TRVs, such as those for PCBs and chlordane, as illustrated in the attached Excel table.

LWG Response: LWG agrees (however, the LWG does not believe fish and invertebrate TRVs can be used interchangeably for all chemicals). The benthic toxicity approach is considered the primary line of evidence. Following the evaluation of the Round 2 toxicity data, other lines of evidence (e.g., the tissue residue approach), and the relevance and uncertainty associated with using such lines of evidence will be discussed in context of the toxicity results.

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